DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
7500 Standish Place (HFV-210)
Rockville, MD 20855

VETERINARY ADVERSE DRUG REACTION, LACK OF EFFECTIVENESS, PRODUCT DEFECT REPORT

(Forward to address at left. Attach all correspondence that pertains to this reaction)

Form Approved: OMB No. 0910-0012
Expiration Date: January 31, 1997

NOTE: This report is required by law (21 CFR 510.300). Failure to report can result in withdrawal of approval of the application.

1. REPORT SOURCE AND ADDRESS *(Mfr., Distr.)*

2. DATE SENT TO FDA *(Month, day, year)*

3. TYPE OF REPORT
☐ INITIAL
☐ FOLLOW UP TO REPORT OF *(Give Date)* _____

4. NAME, ADDRESS AND PHONE NO. OF ATTENDING VETERINARIAN *(In confidence)*
(____) ___-____

5. NAME OR CASE IDENTIFICATION OF OWNER *(In confidence)*

6. TRADE NAME AND GENERIC NAME(S) OF ACTIVE INGREDIENT(S) *(Include dosage form and strength - Ex., tab, 500 mg.)*

7a. NAME OF MANUFACTURER

b. NADA NO.

8. LOT NUMBER

9. DOSAGE ADMINISTERED AND ROUTE *(Ex. 250 mg., q 12 h, p.o.)*

10. DATE(S) OF ADMINISTRATION

11. ILLNESS/REASON FOR USE OF THIS DRUG

12. DRUG WAS ADMINISTERED BY
☐ VETERINARIAN, STAFF ☐ OWNER, OTHER

13. NUMBER OF ANIMALS IN THIS INCIDENT

a. TREATED WITH DRUG	b. REACTED	c. DIED

14. REACTING ANIMALS

a. SPECIES	b. BREED

c. AGE	d. WEIGHT

e. SEX
☐ FEMALE ☐ MALE ☐ PREGNANT ☐ NEUTERED

15. CONCOMITANT MEDICAL PROBLEMS

16. OVERALL STATE OF HEALTH AT TIME OF REACTION
☐ GOOD ☐ FAIR ☐ POOR ☐ CRITICAL

17. DID ANY NEW ILLNESS DEVELOP OR DID INITIAL DIAGNOSIS CHANGE AFTER SUSPECT DRUG STARTED?
☐ NO ☐ YES *(Explain)*

18. CONCOMITANT DRUGS ADMINISTERED

NAME OF DRUG	ROUTE	DOSAGE REGIMEN	DATE(S) OF ADMINISTRATION

FOR FDA USE ONLY

1._____ ☐ D ☐ NAI
2._____ ☐ PR ☐ AI
3._____ ☐ PO ☐ AP
4._____ ☐ R ☐ AL
5._____ ☐ NC
6._____
T._____

☐ I.L. ☐ CR ☐ CONT

COMMENT

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